

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0102]

Robert Ray Courtney; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Robert Ray Courtney from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Courtney was convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act. Mr. Courtney failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective [insert date of publication in the FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

DMB

Display Date 10-17-03

Publication Date 10-20-03

Certifier R. LEDESMA

FOR FURTHER INFORMATION CONTACT:

Nicole K. Mueller,
Center for Drug Evaluation and Research (HFD-7),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

On February 26, 2002, Mr. Robert Ray Courtney entered into an agreement pleading guilty to eight counts of tampering with consumer products in violation of 18 U.S.C. 1365(a) and (a)(3), and six counts each of misbranding and adulterating drugs in violation of sections 301(k) and 303(a)(2) of the act (21 U.S.C. 331(k) and 333(a)(2)). On December 5, 2002, the U.S. District Court for the Western District of Missouri sentenced Mr. Courtney to the maximum 30 years in prison and required Mr. Courtney to pay a fine of \$25,000 and \$10.4 million in restitution for diluting drugs he dispensed to his pharmacy customers. Such drugs included the chemotherapy medications Gemzar (gemcitabine) and Taxol (paclitaxel).

At the time of Mr. Courtney's criminal actions, he was a pharmacist and owner of Courtney Pharmacy, Inc., d/b/a Research

Medical Tower Pharmacy, a company that operated two pharmacies: Research Medical Tower Pharmacy in Kansas City, MO, and Courtney Pharmacy in Overland Park, KS. Among other things, Mr. Courtney was responsible for mixing, preparing, labeling, and distributing intravenous drug mixtures.

In 2001, the Federal Bureau of Investigations (FBI) and FDA set up an investigation that revealed that certain medications Mr. Courtney dispensed were far less potent than the medications ordered by prescribing physicians. One drug sample contained less than 1 percent of the prescribed amount. The investigation resulted in the filing of a complaint on August 14, 2001, charging Mr. Courtney with adulteration and misbranding. It was eventually determined that more than 4,000 patients may have had their prescriptions diluted by Mr. Courtney over a 10-year period. The investigation and admissions by Mr. Courtney culminated in his guilty plea to all 20 counts of the indictment.

As a result of this conviction, FDA served Mr. Courtney by certified mail on May 16, 2003, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Courtney an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that

Mr. Courtney was convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act. Mr. Courtney was provided 30 days to file objections and request a hearing. Mr. Courtney did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

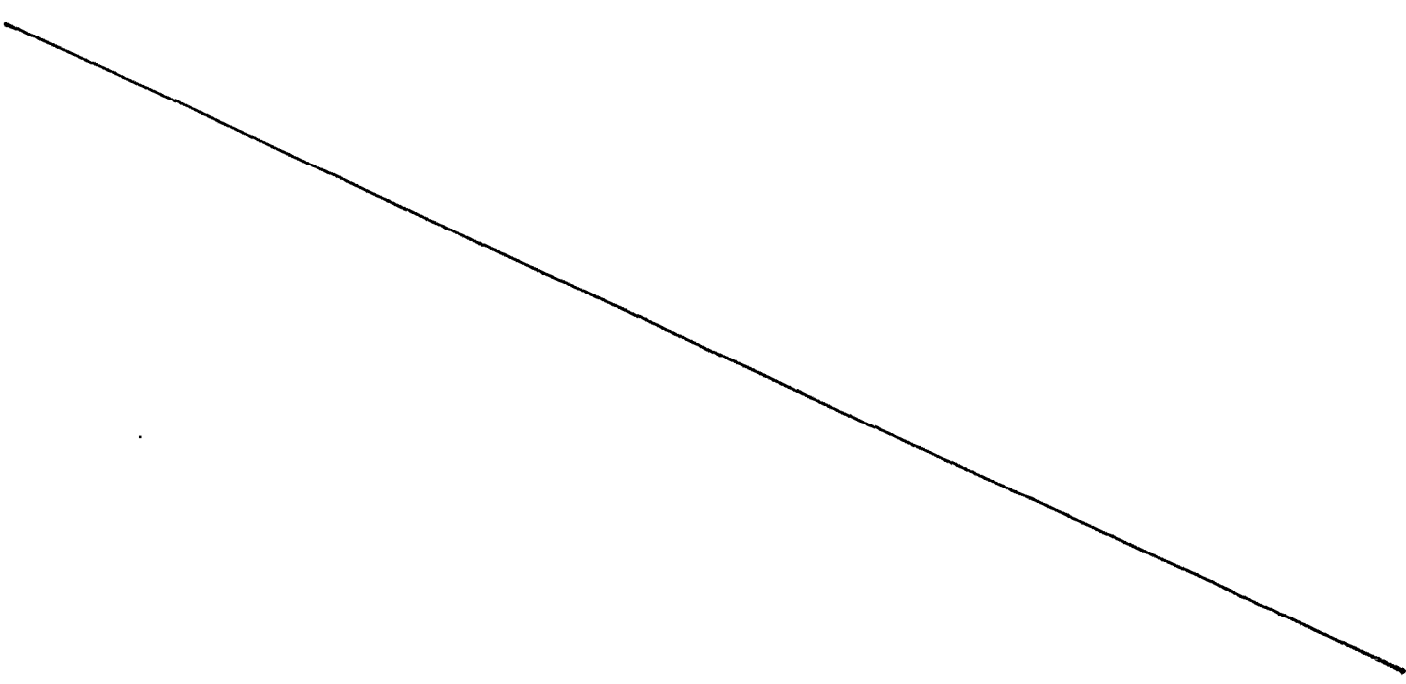
II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Robert Ray Courtney has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

As a result of the foregoing finding, Mr. Robert Ray Courtney is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective [insert date of publication in the FEDERAL REGISTER], (see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application

who knowingly uses the services of Mr. Courtney, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Courtney, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Courtney during his period of debarment.

Any application by Mr. Courtney for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 03N-0102 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these



submissions is governed by 21 CFR 10.20(j). Publicly available
 submissions may be seen in the ^{Division of} ~~Dockets Management Branch~~ between
 9 a.m. and 4 p.m., Monday through Friday.

B Bodo
 10-7-03

Dated: 10/1/03.

OCT 1 2003

Janet Woodcock, M.D.
 Director, Center for Drug Evaluation and Research

B. Bodo 10-7-03

CERTIFIED TO BE A TRUE
 COPY OF THE ORIGINAL

Ryan Adams

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B Bodo 10-8-03